From: John Hebert Dan Peacock To:

Cc: Gene Benbow; Jennifer Gaines; Bill Jacobs

Subject: Re: Fw: Amendments for several products (100' restriction, etc.)

Date: 05/31/2012 08:58 AM

Dan....I wrote the original email. You should have responded to me. He was just offering his opinion that's it. And now I have yours.....

thanks. john

▼ Dan Peacock---05/31/2012 07:04:32 AM---Gene, What products are they complaining about and what are the facts?

From: Dan Peacock/DC/USEPA/US

To: Gene Benbow/DC/USEPA/US@EPA
Cc: Jennifer Gaines/DC/USEPA/US@EPA, John Hebert/DC/USEPA/US@EPA, Bill Jacobs/DC/USEPA/US@EPA

Date: 05/31/2012 07:04 AM

Subject: Re: Fw: Amendments for several products (100' restriction, etc.)

Gene,

What products are they complaining about and what are the facts?

We need to make them have the label text for PPE that the data require. Otherwise, we aren't doing our job.

Liphatech can always redo a study if the earlier one was done incorrectly.

In my experience with re-registration of rodenticides, we updated the labeling of all products to conform to the underlining data. That was the purpose of the process, to bring all product up to current standards.

During re-reg, Tom complained about their PPE for one group of product. However, once Tom was shown the facts, he backed down. He will again if the facts are against him.

Here is what appears to be happening with LiphaTech:

- Liphatech's marketing folks, who probably are unfamiliar with the regulatory process, think that a competitor has an unfair advantage.
- Marketing Dep complains to regulatory Dep
- Regulatory Dep complains to RD.

What should be happening here is to investigate the facts and respond accordingly. Otherwise, Tom the bully, will be encouraged to request even more outrageous things.

That's my take.

Daniel B. Peacock, Biologist

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United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

▼ Gene Benbow---05/30/2012 07:27:47 PM---I'm okay with it not being on the labels. If it makes any difference, not even all Lipha labels h

From: Gene Benbow/DC/USEPA/US

To: John Hebert/DC/USEPA/US@EPA

Cc: Dan Peacock/DC/USEPA/US@EPA, Jennifer Gaines/DC/USEPA/US@EPA

Date: 05/30/2012 07:27 PM

Subject: Re: Fw: Amendments for several products (100' restriction, etc.)

I'm okay with it not being on the labels. If it makes any difference, not even <u>all</u> Lipha labels have this PPE. In the stack of amendments I have on my desk for the 100' thing, there are 1-2 that (for whatever reason) do not have this PPE (LS shirt and long pants).

So, if we decide to keep it on the labels, we'll have to have Tom change these other 2 labels to <u>add</u> the PPE. This would definitely make things interesting with these products -- regardless, I'll support whatever you guys decide (obviously).

Gene

----John Hebert/DC/USEPA/US wrote: -----

To: Gene Benbow/DC/USEPA/US@EPA, Jennifer Gaines/DC/USEPA/US@EPA, Dan

Peacock/DC/USEPA/US@EPA From: John Hebert/DC/USEPA/US Date: 05/30/2012 05:12PM

Subject: Fw: Amendments for several products (100' restriction, etc.)

OK...Here we go again with Lipha. Tom is complaining that for his products we are requiring PPE (long sleeve pants/shirts) that is different than on competitor labels. So, it looks like the data they cited during product rereg is Category III (dermal) for difethialone and bromadiolone. But I think the precautionary labeling is probably overkill. I really don't think this product is Category III. So what do you think.....? Should we drop the PPE? Let me know what you think. Thanks.

John Hebert, PM7 Insecticide-Rodenticide Branch Registration Division Office of Pesticide Programs 703-308-6249

---- Forwarded by John Hebert/DC/USEPA/US on 05/30/2012 04:31 PM -----

From: Thomas Schmit <SchmitT@liphatech.com>

To: John Hebert/DC/USEPA/US@EPA

Cc: Ted Bruesch <BrueschT@liphatech.com>, Michele Brunlinger

<brunlingerm@liphatech.com>, Jim Doll <dollj@liphatech.com>, Ray Finke
<finker@liphatech.com>, Gene Benbow/DC/USEPA/US@EPA, Carl Tanner
<TannerC@liphatech.com>, Gene Benbow/DC/USEPA/US@EPA, Jennifer
Gaines/DC/USEPA/US@EPA, Kelly Bornhofer <BornhoferK@liphatech.com>

Date: 05/14/2012 11:13 AM

Subject: RE: Amendments for several products (100' restriction, etc.)

Hello John,

I understand that this guidance is shown in the label review manual.

We suggest that this guidance may be appropriate for pesticide products that are sprayed or broadcast, or applied by some other method that might result in contact with arms and legs.

However, our solid baits for commensal rodent control are not sprayed, broadcast,

scattered about, etc. Rather, they are required by the label to be placed (wearing waterproof gloves) placed into bait stations or enclosed locations such as a wall void or burrow, making it highly unlikely that an applicator will contact the bait with arms or legs. This PPE requirement does not appear to be necessary because the solid bait form and the directions for use essentially preclude such exposure.

Please confirm your decision and let us know how we should submit revised labels, if necessary.

Thanks - Tom

From: John Hebert [mailto:Hebert.John@epamail.epa.gov]

Sent: Friday, May 11, 2012 4:39 PM

To: Thomas Schmit

Cc: Ted Bruesch; Michele Brunlinger; Jim Doll; Ray Finke; Gene Benbow; Carl Tanner; Gene

Benbow; Jennifer Gaines

Subject: RE: Amendments for several products (100' restriction, etc.)

Tom - Based on the acute toxicity data supporting your difethialone (MRIDs 40268905 and 45179602) and bromadiolone (MRID 43905208) registrations, the dermal toxicity category for your products is **Category III**. Based on EPA's Label Review Manual (see section 7-9), the PPE - "long sleeved shirts and long pants" is appropriate for your products. You can cite other relevant acute dermal toxicity data or provide a new study if you believe your products are not Category III for this route of exposure. Please let me know if you have any questions.

John Hebert, PM7 Insecticide-Rodenticide Branch Registration Division Office of Pesticide Programs 703-308-6249

yv+LAH8AAAAAAAASW5hY3RpdmUgaGlkZSBkZXRhaWxzIGZvciBUaG9tYXMgU2NobWl0IC0tLTA0 LzIwLzIwMTIgMDQ6MTI6MjcgUE0tLS1Hb29kIGFmdGVybm9vbiBNci4gQmVuYm93LCBJIGFtIHJl cGx5aW5nIHRvIHlvdXIgbWVzc2FnZSBvbg== Thomas Schmit ---04/20/2012 04:12:27 PM--- Good afternoon Mr. Benbow, I am replying to your message on behalf of Michele, as I am the person he

From: Thomas Schmit < SchmitT@liphatech.com >

To: Gene Benbow/DC/USEPA/US@EPA, John Hebert/DC/USEPA/US@EPA

Cc: Carl Tanner < "> Jim Doll < "> Michele Brunlinger < brunlingerm@liphatech.com>, Ray

Finke <finker@liphatech.com>, Ted Bruesch <BrueschT@liphatech.com>

Date: 04/20/2012 04:12 PM

Subject: RE: Amendments for several products (100' restriction, etc.)

Good afternoon Mr. Benbow,

I am replying to your message on behalf of Michele, as I am the person held responsible for label language by my company management.

Following the "mitigation measures" label revisions made for all rodenticides